

### **REMARKS**

Upon entry of the amendment, claims 1-28 will be pending in the application. Support for new claim 28 appears in, e.g., paragraph 25. No new matter is added.

#### **35 U.S.C. § 103 Rejections Overcome**

Claims 1-27 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 5,487,901 ("Conte") in view of U.S. Patent No. 6,599,284 ("Faour"). Specifically, the Examiner alleges that Conte discloses a pharmaceutical tablet composed of an upper layer containing an active ingredient, formulated for immediate release, an intermediate layer that does not contain any active agents and is formulated with polymers as a semipermeable membrane, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being *almost* completely coated with an insoluble polymeric coating (*emphasis added*). (See, Office Action at pages 2-3). The Examiner acknowledges that Conte does not teach or suggest a laser incision. (See, Office Action at page 3). The Examiner submits that Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredients, an intermediate layer forming a semipermeable membrane and an inner layer or core containing active ingredient, and the dosage form comprises a passageway formed by a laser incision. (See, Office Action at page 4). The Examiner submits that it would have been obvious to a person of ordinary skill in the art to disclose a tablet system comprising two external layers and a third layer with laser incisions on the surface as taught by Conte in view of Faour. (See, Office Action at page 4). Applicants disagree.

Applicants submit that there the Examiner has not established a *prima facie* case of obviousness for claims 1-27 in light of the teachings of Conte and Faour. Further, Applicants assert that claims 1-27 are based upon unexpected results that there is no motivation to combine the teachings of Conte and Faour.

#### *No Prima Facie Case of Obviousness*

Prior art references need not teach or suggest all the claim limitations; however, Office personnel must explain why the differences between the prior art and the claimed invention

would have been obvious to one of ordinary skill in the art.<sup>1</sup> In the instant case, the Office Action fails to appreciate the differences between the prior art and the claimed invention.

Applicants submit that Conte and Faour, alone or in combination teach or suggest delimiting an area of the polymeric material of a geometric shape and predetermined dimensions as required by the pending claims. As acknowledged by the Examiner, Conte does not teach or suggest a laser incision, and, while the passageway described in Faour can be formed by controlled laser perforation (*see Faour* at column 13, lines 48-50), it does not generate one or more laser incisions delimiting an area of the polymeric material of a geometric shape and predetermined dimensions as required by the pending claims. Thus, there is no proper *prima facie* case of obviousness.

#### *Unexpected Results*

Applicants assert that a person having ordinary skill in the art reviewing the cited references would not have arrived at the subject matter of claims 1-27 because using the laser incision, which increases the stability of the tablet by protecting the ingredients contained in the tablet from humidity and oxidation prior to administration of the formulation, is based on unexpected results, which is evidence that the methods of these claims is non-obvious over Conte and Faour.

Applicants submit that the incision(s) delimited in the film coating of the tablet of claims 1-27 remains intact before contact with aqueous fluids. Specifically, the laser beam etches an incision in the film polymeric coating that delimits an area of geometrical shape and of predetermined dimensions, and the incision notches the film coating without interfering with the underlying tablet. (*See*, Specification at page 6, lines 3-10). The area delimited by the laser incision is not removed until contact with an aqueous fluid. (*See*, Specification at page 6, lines 10-14).

Whereas the tablet in Conte do not provide any such protection of the active ingredients as the raised tops of the tablets are removed with an abrading system which scrapes out the raised tops leaving the active ingredient of the entire area exposed. (*See*, Conte at Column 6, lines 1-4). Applicants submit that the tablet of the claimed invention has the unexpected properties, as Conte does not provide a method to stabilize the active ingredient exposed by the

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<sup>1</sup> Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*, Federal Register / Vol. 72, No. 195, Page 27528 / Wednesday, October 10, 2007.

abrading process. (*See*, Specification at page 6, lines 24-27 and Declaration under 37 C.F.R. § 1.132 of Ubaldo Conte submitted on March 10, 2008).

Faour does not cure the deficiencies of Conte as Faour teaches that the formation of the passageway can be formed by controlled laser perforation. (*See* Faour at column 13, lines 48-50.) The laser in Faour does not increase the stability of the tablet by protecting the ingredients contained in the tablet from humidity and oxidation prior to administration of the formulation.

Thus, Applicants submit that the methods of claims 1-27 are based on unexpected properties and thus are non-obvious over Conte and Faour.

*No Motivation to Combine the References*

Applicants also assert that one of ordinary skill in the art would not have had motivation to combine the teachings of Conte and Faour. One of the requirements to make a *prima facie* case for obviousness is that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Deputy Commissioner of Patent Operations issued a memorandum on May 3, 2007 following the Supreme Court decision on *KSR Int'l Co. v. Teleflex, Inc.* stating the following:

[I]n formulating a rejection under 35 U.S.C. § 103(a) based upon a combination of prior art elements, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.

Applicants further submit that the Examiner has merely asserted that a skilled artisan would have been motivated to combine the above references without identifying where in the references either explicit or implicit motivation can be found to support the rejection. Specifically, the Examiner submits that one of ordinary skill in the art would have been motivated to make the claimed tablet by combining Conte and Faour because it is useful in providing an immediate release of an active ingredient, followed by a delayed release, as exemplified in Conte. (*See*, Office Action at page 3).

However, Applicants submit that one of ordinary skill in the art could not find a motivation to combine Conte and Faour either in the references themselves or in knowledge generally available in the art as Conte teaches a formulation where a portion of the coating is removed only when the tablet is exposed to an aqueous environment upon administration. In contrast, Faour discloses an osmotic device with a core that is surrounded by a semipermeable

membrane with a passageway that delivers the active agent to an environment of use in a controlled manner.

The Examiner has only alleged that the references can be combined to arrive at the present invention. The mere fact that references can be combined or modified, however, does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. (See M.P.E.P. § 2143.01 (III)). That is, a rejection based on a *prima facie* case of obviousness is improper without a motivation to combine the references. The Office Action combines facts and attempts to provide a motivation to combine the references without identifying the source of the motivation. The desirability of the combination is not suggested in any of the references cited by Examiner. Accordingly, the Office Action has also failed to establish a *prima facie* case of obviousness because the cited references do not provide either explicit or implicit motivation to combine or modify the teachings of the references to arrive at the present invention.

In light of the above, Applicants respectfully submit that the Office Action fails to present sufficient reason why a person of ordinary skill in the art would have combined the teachings of Conte and Faour.

For all of the above reasons, the Applicants submit that claims 1-27 are not obvious over the teachings of Conte and Faour and respectfully request that this rejection be withdrawn.

New claim 28 is further non-obvious in view of Conte and Faour because it expressly requires that one or more laser incisions delimit directly on the external layers of the polymeric material. There is no suggestion of this feature in the cited references. Conte, as discussed above, lacks any teaching of a laser incision. Faour, in turn, does not teach or suggest using a laser to create an opening that is directly on a polymeric membrane. Instead, this reference teaches irradiation of a semi-permeable membrane surrounding an active agent-containing core on an osmotic device. Conte explains that the passageway is made using this semipermeable wall (col. 13, lines 48-51):

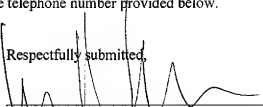
The preformed passageway (5) in the semipermeable wall is generated by mechanical means, such as perforation by a laser or drill, or any other similar method known to those of ordinary skill in the art.

Claim 28, however, in requiring that the laser incisions delimit directly on the walls of the polymeric material excludes a semi-permeable wall or membrane. Since there is no

suggestion in Faour for using laser irradiation in the absence of a semi-permeable wall or membrane, claim 28 is non-obvious over the cited references for at least this reason.

Applicants submit that this paper is fully responsive and that the application is in condition for allowance. Should any questions arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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